UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-29,32,33 and 36-63* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-29, 32-33, 36-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

SAM RIMELL
PRIMARY EXAMINER

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 25-29, 32-33 and 36-63 are rejected under 35 U.S.C. 102(e) as being

anticipated by Bond et al. (U.S. Patent 6,177,940).

Claim 23: Bond et al. illustrates a data processing mechanism as shown in FIG. 1. The

data processing mechanism is structured to gather health information from a patient by using an

interviewing mechanism that asks specific questions to the patient (FIGS. 18A-18G). The

interview mechanism is logic driven and branching in the sense that different patient answers

will lead to differing lines questions (col. 17, lines 63-65). The interview includes a plurality of

interview elements (each screenshot of FIGS. 18A-18G is an interview element). The

interviewing system also implements screening questions, which are the questions directed to the

physician used to set up the interview (See FIG. 16). For example, the screening questions are

those shown in (1602) and (1602') in FIG. 16 and determine issues which are important to the

patient. Each one of the items "Upper Extremity", "Spine" and "Lower Extremity" are thresholds

which can be selected by the physician and are linked to the creation of specific interview

elements (screenshots of FIGS. 18A-18G). The template of FIG. 16 is thus an interview

configuration mechanism that can set and re-set thresholds. For example, if the threshold "Upper

Extremity" is selected, this becomes a default threshold. This default threshold can be changed to

"Spine" or "Lower Extremity", thus changing a default setting. The patient responses actually

define the scope and depth of the interview (col. 17, lines 63-65). The system can analyze prioritize and arrange healthcare information for output in a report. The tool used for the analyzing and prioritizing is the report selection tool of FIG. 5, with sample reports shown in FIGS. 8A and 8B. The interview configuration selection mechanism is shown in 1602 of FIG. 16, where the physician selects a particular interview configuration. The system further includes a storage database (1516 in FIG. 15).

Claim 25: FIG. 16 of Bond et al. specifies that the patient interviews are developed from a set of modules (1602, 1602'). Each module corresponds to a specific subject matter area, such as physical symptoms in specific body areas. Each interview inherently includes a certain degree of detail.

Claim 26: The interview elements are the screenshots of FIGS. 18A-18G. Each optional answer in the screenshot represents a threshold. A selection of an answer by a patient causes that answer to be entered in the system. Each threshold is considered "on/off" in the sense that the thresholds are either selected ("on") or not selected "(off").

Claim 27: The data processing system is programmed to implement an interview. The interview configuration profile is the set of selections made by the physician at FIG. 16 to set-up an interview. The profile includes thresholds, such as "Upper Extremity", "Spine" and "Lower Extremity". A default threshold can be an initial selection, such as the selection of "Upper Extremity" in FIG. 16. This can be modified to a different threshold, such as "Spine". The executed interview is a direct reflection of the thresholds selected by the physician. As seen in FIGS. 18A-18G, the patient is ultimately presented with detailed questions about symptoms or issues.

Claim 28: The interview questions presented to the patient are custom selected for that patient based upon particular medical problems (col. 17, lines 51-53).

Claim 29: The first two paragraphs of claim 29 are addressed to the actual content of the questions, which carry no patentable weight (The content of the actual questions are considered non-functional descriptive material; MPEP 2106, Section VI; second paragraph). FIG. 18B illustrates questions presented to the patient about relative importance of symptoms. FIG. 18F deals with questions of severity while FIG. 18D deals with time profiles. The questions actually presented are based upon the profile of questions established by the physician.

Claim 32: In Bond et al., any of the questions posed in FIGS. 18A-18G read as patient viewpoint modules since each of these screens presents a question to a patient.

Claim 33: In Bond et al., FIGS. 18A-18G, the patient is queried about multiple symptoms, such as diabetes and hear disease (FIG. 18C); weakness (FIG. 18D) and pain (FIG. 18F).

Claim 36: As seen in FIGS. 18C, 18D, and 18F of Bond et al., the patient can be queried about multiple symptoms. Since the system asks follow on questions based on specific answers, it is apparent that the system of Bond et al. associates symptoms together and asks more targeted questions as more data is provided. For example, an indication that a patient takes pain medication may lead to associated questions about the exact nature of the pain or location of the pain.

Claim 37: As seen in FIG. 5 of Bond et al., the electronic interview with the patient can collect medical data (510, 512) and psychosocial data (514).

Claim 38: As described at col. 18 ,lines 55-58, the patient's responses are scored to

obtain a quantitative score. The quantitative score obtained is readable as a "severity index".

Claim 39: Any of the questions posed to the patient in FIGS 18A-18G of Bond et al. are

related to quality of life. As seen from col. 18, lines 19-27, the patient may be asked an initial set

of questions (col. 18, line 20), then, based on the answers to those questions, asked more detailed

questions.

Claim 40: Col. 18, lines 47-53 of Bond et al. indicate that the interview may be

conducted at one single session or conducted over multiple sessions. The "residual modules" can

be any set of questions that are posed at subsequent sessions.

Claim 41: FIGS. 8A and 8B illustrate patient reports that may be generated.

Claim 42: The information collected at a follow up interview in the Bond et al. system

could inherently include change data involving changes in symptoms (col. 18, line 52). Interview

questions may be repeated (col. 18, line 49). Col. 18, lines 47-53 describe follow up interviews

presented.

Claim 43: In Bond et al., the interview questions may inquire about the status of the

patient and changes in symptoms over time (col. 18, lines 51-52). The patient may also be

queried about past medical conditions (FIG. 18C). Any of the questions presented to the patient

in the screens of 18A-18G pertain to the patient's quality of life, and thus are considered to be

HRQL type questions.

Claim 44: In Bond et al., once the patient data is collected, it is stored in a database for

future access. The access to this data is achieved through the physician's menu page illustrated in

FIG. 9B. Information about problem areas (button 928), symptoms or medical condition (button 926) can be accessed. As seen in FIG. 9B, the data presentation can be in a medical problem oriented manner (936). The data can be presented by currency (past medical problems by button 928 and current medical problems by button 926). A hierarchy of information and medical problems can be presented (936). Comments by the physician may be entered into the system.

Claim 45: The data entered by the patient can be electronically edited in the sense that it can be converted into a report, such as the reports shown in 8A and 8B. The editing is perfomed by the tool of FIG. 5, which specifies the particular data to be used in the report.

Claim 46: In FIG. 9B of Bond et al., information on past health information (928) and current health information (926) can be accessed.

Claim 47: FIG. 9B of Bond et al. is a template used by the physician for entering health information. The actions by the physician, such as an examination procedure or treatment procedure can be set up as a menu of protocols and recorded into the database by the physician (See FIG. 13, element 1302 and col. 15, lines 42-45).

Claim 48: In Bond et al., any of the information entered by the physician into the database, such as selected treatment protocol can be printed at a printer to produce a report (114).

Claim 49: As seen in FIG. 10A of Bond et al., the system can maintain a log of examination dates. A log of examination constitutes a schedule, and reads as a programmed mechanism for scheduling. Patient contact information, such as telephone number or address is inherently collected whenever a patient schedules a medical appointment. The contact with the patient may be made by a clinic visit.

Claim 50: As seen in FIG. 6C of Bond et al., steps 628, 634 and 636 define an administrative function where the physician's treatment plan is converted and renamed into CPT codes (ICD-9 is a known standard for CPT codes) and generate a list of CPT codes and costs associated with these codes. The list of codes is a "health problem list". The usage of CPT codes to define and describe medical conditions is a known requirement of JCAHO standard practices.

Claim 51: See remarks for claim 50. The coding is the establishment of the CPT codes for specific treatment provided by the physician. The expense coding is the association of cost with the CPT code, as performed at step 636.

Claim 52: FIG. 18B gives an example interview question. A non-response to the question is not offered as an option. The appropriate responses are already designed by the system. For example, the appropriate responses "Never", "Occasionally", "Less than once a day", "Once a day" and "More than once a day" are already designed into the system.

Claim 53: FIG. 18G in Bond et al. illustrates the collection of quality management data from the patient. This pertains to how satisfied the patient is with the treatment.

Claim 54: The collected quality management data is stored in the database and can be accessed by the physician. The quality management data can be collected after treatment.

Claim 55: The quality management question described by FIG. 18G of Bond et al. probes patient satisfaction.

Claim 56: Within the context of a physical system, no patentable weight is attributed to when the system is being used, such as before a doctor visit or after a doctor visit.

Claim 57: The system of Bond et al. is a patient information system that collects information from patients. The collection system reads as the claimed "mechanism". Parts (a)-(e) appear to be intended usages of the mechanism and methods of using the mechanism which carry no patentable weight in claims addressed to a physical system.

Claim 58: The system of Bond et al., collects data regarding patient assessment, clinical outcomes and patient treatments. How this data is actually used carries no patentable weight in the context of claims addressed to a physical system.

Claim 59: The system of Bond et al. collects and structures patient information and tracks patient responses to questions. How the information is used, such as in a corporate wellness program, carries no patentable weight.

Claim 60: The conditional threshold is optionally recited in claim 26, and thus carries no patentable weight since it is not necessarily part of the invention.

Claim 61-62: The interview thresholds are illustrate in FIG. 16. Three such thresholds are "Upper Extremity", "Spine" and "Lower Extremity". Selection of the these thresholds will dictate the nature of the interview elements (the screenshots of FIGS. 18A-18G).

Claim 63: FIG. 5 is a tool created by the programming logic that will select particular findings using particular criteria, such as the criteria 508-516 shown in FIG. 5. A selection of particular findings is considered to a flagging of particular information. Tool 504 in FIG. 5 calls for the input of a sort criteria, which will summarize information about patients. Any information collected and calculated can be displayed, including the display of responses and scores (step 728 in FIG. 7B).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
such that the subject matter as a whole would have been obvious at the time the invention was made to a person
having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al. in

view of Gray (U.S. Patent 6,149,585).

Claim 24: Claim 24 differs from Bond et al. in that it does not disclose a server to access

the saved interview information stored in a database (schematically illustrated at 1516 in FIG.

15). Gray teaches (FIG. 1) that an Internet web server (130) can permit interactive entry, review

and analysis of medical data. It would have been obvious to one of ordinary skill in the art to

modify Bond et al. to permit interactive entry, review and analysis of medical data via an Internet

server so as to permit convenient access to different system users as taught by Gray.

Remarks

Applicant's amendments have overcome the previous grounds of rejection under 35 USC

112.

Applicant's arguments and amendments generally pertain to the feature of having

thresholds, such as recited in the current version of independent claim 23. During the interview

of March 1, 2004, Examiner and applicant's representative Todd Taylor had a discussion

regarding the feature of using thresholds as they pertained to Figure 7C of applicant's invention.

Examiner pointed out that Figure 7C illustrated software programming that included a series of

different threshold levels, when triggered by the patient, lead to different lines of questioning presented to the patient.

The present set of claims do advance prosecution by defining the general presence of threshold values, but do not clearly indicate that threshold values triggered by the patient answers lead to different branches of questioning presented to the patient. The present claims, and in particular, claim 23, do not establish multiple threshold values and different branches of questioning presented to the patient based upon the triggering of one of the specific thresholds by a specific answer from the patient. In Bond et al., the physician selects threshold values in FIG. 16, which in turn lead to a specific set of questions presented to the patient.

In addition, the claims have been broadened by not reciting the presence of a server system in claim 23.

Accordingly, the present claims are rejected primarily under 35 USC 102(e) as being anticipated by Bond et al. Claim 24 is rejected under 35 USC 103(a) as being obvious in view of Bond et al.and Gray.

This office action is made non-final.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.

Sam Rimell
Primary Examiner
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